FACT SHEET

Inspiring the Future of Ophthalmic Clinical Development

Dry Eye and Ocular Surface

Over the last 40+ years, Ora has been at the forefront of supporting our customers in developing innovative products for the treatment of ocular surface disease. We are driven to provide insights on trial designs, endpoint selection, recruitment strategies, as well as methods/models to reduce data variability. The team at Ora has been instrumental in partnering with our customers to achieve over 80 product approvals over the years and has supported several approvals in the treatment of Dry Eye Disease.

Areas of Expertise

- Adenoviral Conjunctivitis
- Bacterial Conjunctivitis
- Blepharitis
- Dry Eye
- Herpes Keratitis
- Meibomian Gland Dysfunction
- Neurotrophic Keratitis
- Post-Cataract Inflammation
- Presbyopia
- Meibomian Gland Dysfunction

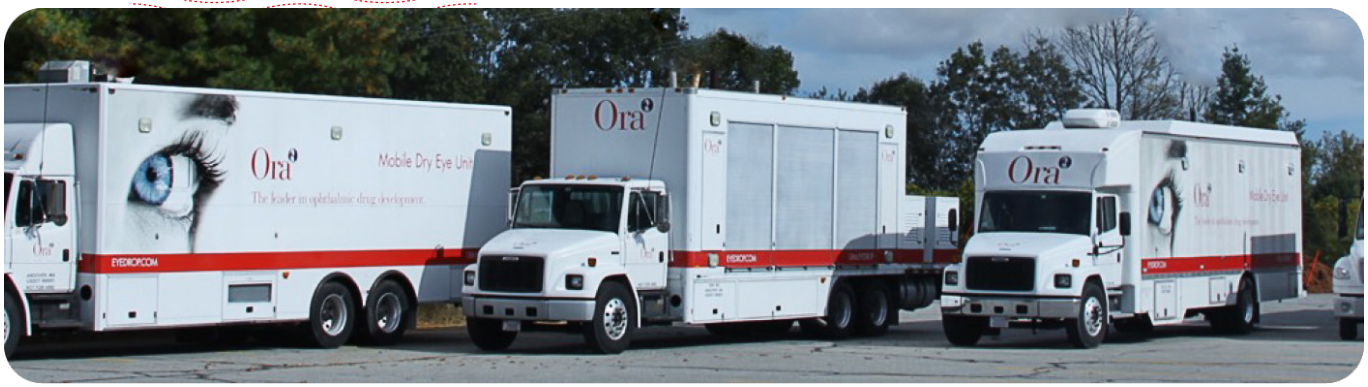
George W. Ousler III
Senior Vice President
of Anterior Segment

As Ora's Senior Vice President of Anterior Segment, George Ousler oversees all Dry Eye/Ocular Surface Disease clinical programs, lending his therapeutic expertise to see each development project through to completion. With his 25+ years of pioneering pharmaceutical development in Dry Eye, George continues to develop clinical models and regulatory pathways for the evaluation of Dry Eye therapies. The Anterior Segment Department at Ora consists of more than 100 team members who work with global clients in the North America, Europe, and Asia.

George has authored more than 300 publications in Dry Eye and holds several patents on techniques, formulations, and methods in the Dry Eye space. Often, George is requested to consult on worldwide drug development and registration, and frequently interacts with many regulatory agencies, including the US FDA (Food and Drug Administration), the European Medicines Agency, the China Food and Drug Administration, and the Medical Device Agency of Japan.

George serves on several noted Dry Eye research committees and Scientific Advisory Boards. He is a member of several ophthalmic professional organizations and is also a reviewer for numerous scientific journals.

"With the approach Ora brings to scientific understanding and expertise coupled with novel methods and models to optimize success, we have a tried-and-true process to be a strong collaborator in the development of your therapeutic. Our team's unparalleled ophthalmic experience allows for the utmost diligence in reducing variability, maintaining protocol adherence, ensuring your trial remains on-time and within budget. It has been a tremendous honor to partner with our clients in developing novel therapies to treat ocular surface disease and reduce the burden of disease for millions of patients worldwide. We look forward to supporting the discovery and approval of next generation medicines for the Anterior Segment."



Ora CAE®
Dry Eye Challenge

Ora's CAE® (Controlled Adverse Environment) Dry Eye Challenge model exposes study participants to regulated changes in humidity, temperature, airflow, and visual tasking, forcing the ocular surface to react to added stress. This controlled environmental stress creates a consistent response, which is reproducible over time. Data derived from the CAE® model offers greater precision in evaluating the efficacy of your drug — with fewer patients, fewer sites, and less time.

Ora CAE® Dry Eye Challenge creates the ideal paradigm for identifying:

- An enriched population of Dry Eye patients with modifiable signs and symptoms — more homogenous patient population
- Standardized endpoints for intervention that show relevant change.

We provide a menu of trial designs and will work with you to determine the right approach for your product:

- Environmental
- CAE® model patient screening and enrichment
- Full CAE® trial with screening/patient enrichment and CAE®—specific endpoints

The Ora CAE® model can be:

- Tailored to the MOA of the therapeutic to be tested.
- Used at multiple sites across the globe.

Our Mobile Dry Eye Units enable multi-center Dry Eye trials while still reducing clinical variables among sites. With Ora, you can bring your clinical trial to the patient.

20,000+
Patients Recruited

85+
Products Approved

Trusted innovators in Dry Eye for 45 years

With Scientific Rigor being one of the pillars of what makes Ora different, our dedicated anterior segment team's deep understanding of Dry Eye disease can give your treatment the extra support it needs to meet the unmet needs of patients. All the Ora Anterior Segment project managers have delivered Dry Eye projects for sponsors of all sizes from around the world, allowing you to benefit from this indication specific experience. Stress creates a consistent response, which is reproducible over time. Data derived from the CAE® model offers greater precision in evaluating the efficacy of your drug — with fewer patients, fewer sites, and less time.

Supporting you from concept to approval

Ideation → Preclinical → CMC → Regulatory Consulting → Clinical Execution

In addition to our Preclinical and Clinical Execution services, Ora's in-house CMC (Chemistry, Manufacturing, and Control) and regulatory experts can guide you through your drug's development journey. Ora's regulatory team creates an individualized strategy to increase the likelihood of success based on your product. Special considerations for this strategy include your product's MOA, unmet medical needs, competitive landscape, and careful attention to the regulatory pathway. We attain strategic relationships with GMP manufacturers and laboratories, as well as consistently facilitate discussions with global regulatory authorities at all phases of development. Ora's regulatory team can take on clinical and regulatory strategy and submissions, along with comprehensive regulatory and medical writing services.

Ora

Ora is a global full-service ophthalmic drug and device development firm with vast capabilities through all steps of clinical research, including preclinical, clinical, CMC & regulatory, and patient and site evaluations. Through Ora's 40+ years of experience, the company has assisted in bringing more than 80 products to market. Ora's team of experts utilizes global regulatory strategies, integrated research operations, and extensive site and patient engagement to accelerate product development in anterior and posterior segment, as well as ophthalmic devices.